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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,952	01/17/2002	Patricia S. Walker	D-2933CIP	2757

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,952	WALKER, PATRICIA S.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9,10,12 and 36-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 9, 10, 12 and 36-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed September 27, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1-4, 6, 7, 9, 10, 12 and 36-45 are pending.

Applicant's amendment filed September 27, 2004 is acknowledged, and applicants' response has been fully considered. Claim 4 has been amended, and a new claim 45 has been added. Therefore, claims 1-4, 6, 7, 9, 10, 12 and 36-45 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claim 4, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's amendment to the claim and applicant's response at pages 6-7 in the amendment filed September 27, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 39 recites the broad recitation a dense material, and the claim also recites preferably solid, or metallic material which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (U. S. Patent 5,183,462) taken with Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58; claims 7 and 41) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal

dose of the toxin was injected into muscle at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 9, 10, 12, 36 and 42-45). However, Borodic does not disclose the use of a needleless syringe. Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (a needleless injection system; the whole document; claims 2, 6, 37 and 40). At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the two references to treat wrinkles and brow furrows by administering botulinum toxin A as taught by Borodic with a Dermojet as taught by Vadoud-Seyedi *et al.* because Vadoud-Seyedi *et al.* indicate the pain injection with a Dermojet is acceptable, and there were neither paresthesias nor other side effects, and suggest the injection of botulinum toxin with a Dermojet is an effective and comfortable technique (page 179, third and last paragraph). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

6. Claims 3, 4, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic in view Vadoud-Seyedi *et al.* as applied to claims 1, 2, 6, 7, 9, 10, 12, 36, 37 and 40-45 above, further in view of McCabe *et al.* (U. S. Patent 5,525,510).

Borodic discloses the injection of an appropriate dose of a botulinum toxin such as pharmaceutical grade botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction (column 4, lines 50-58; claims 7 and 41) and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows, and a sublethal dose of the toxin was injected into muscle at the sites superior border of the forehead and at a

point approximately 15 mms superior to the brow (column 3, line 67-column 4, line 6; column 5, lines 5-19; column 9, lines 42-66; claims 1, 9, 10, 12, 36 and 42-45); Vadoud-Seyedi *et al.* disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (claims 2, 6, 37 and 40); and the combined references teach the treatment of wrinkles and brow furrows by administering botulinum toxin A into muscle with a Dermojet. However, Borodic and Vadoud-Seyedi *et al.* do not disclose the use of a botulinum toxin coated onto the carrier. McCabe *et al.* teach the biological material such as DNA, RNA, proteins or peptides is coated onto the carrier particles such as small gold beads or spheres (column 6, lines 22-35; claims 3, 4, 38 and 39). At the time of invention was made, it would have been obvious that one of ordinary skill in the art to combine the three references to treat wrinkles and brow furrows using the method taught by Borodic and Vadoud-Seyedi *et al.* with botulinum toxin A coated onto the gold sphere taught by McCabe *et al.* because the treatment with neurotoxin coated onto the gold particle would be safer since the high density carrier with small particle size would readily enter living cells without injuring the cells. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

In response, applicant indicates Vadoud-Seyedi *et al.* disclose needleless injection of a botulinum toxin into the sole of a pateint's foot to treat plantar hyperhydrosis, and plantar hyperhydrosis is a condition involving excessive secretions from plantar sweat glands. Sweat glands are located in the dermal layer of the skin (e.g., see Exhibit A) and are innervated by the sympathetic nervous system, a subset of the autonomic nervous system. Vadoud does not disclose, teach, or even suggest the use of a botulinum toxln to treat wrinkles or braw furrows;

Boridic discloses administration of a botulinum toxin by injection using a syringe with a needle, Borodic does not disclose, teach, or even suggest the use of a needleless syringe to deliver a botulinum toxin for any purpose, let alone to treat wrinkles and brow furrows; a person of ordinary skill in the art would not be motivated to combine Borodic and Vadoud, as proposed by the Examiner, because Vadoud only dlscloses the use of a botulinum toxin to interfere with the sympathetic nervous sysrem. In particular, Vadoud only discloses needleless administration of a botulinum toxin to interfere with a neuronal influence on a sweat gland located in the dermal layer of the skin, this actually teaches away from the claimed methods using a needleless injection of botullnum toxin to treat wrinkles or brow furrows by reducing a muscle contraction, and claim 45 specifically states that the amount of botulinum toxin is adminstered to a subdermal muscle tissue in proximity to the wrinkle; as the Examiner has acknowledged, treatment of wrinkles and brow furrows is different and distinct from treatment of other conditions (see September 16, 2003 Office Action, page 3, lines 1-2); claims 3, 4, 38 and 39 are similarly unobvious from and patentable over the combination of Borodic in view Vadoud-Seyedi *et al.* and further in view of McCabe *et al.*; and each of the present dependent claims is separately patenable over the prior art because none of the prior art disclose, teach or suggest the additional features recited in the claims (pages 7-11 of the response).

The response has been considered, however, the argument is not found persuasive because Boridic discloses the treatment of a wrinkle or brow furrows by administering a botulinum toxin using a syringe with a needle into muscles (column 5, lines 5-19) at the sites superior border of the forehead and at a point approximately 15 mms superior to the brow (column 9, lines 42-66), which meet the criteria of claim 45 regarding the adminstration site; and

the secondary reference, Vadoud-Seyedi *et al.* teach a technique of injection using needleless syringe (e.g., a Dermojet), which has advantages as compared to injection with needle, e.g., the technique is safer and the injection with pain level is acceptable. McCabe *et al.* teach the biological material can be coated onto the carrier such as gold beads for needleless injection. Although Vadoud-Seyedi *et al.* teach using botilinum toxin to treat plantar hyperhidrosis, which is a different condition from wrinkle or brow furrows, the reference does disclose the advantages of using a Dermojet in the treatment. Furthermore, the advantage of using needleless injector (e.g., less pain, no risk of infection-safer) is well known in the art and has been stated in Bellhouse's patents (e.g., US. Patent 5,899,880, column 1, lines 61-65), which are incorporated in their entirety by reference in the specification (page 23, lines 17-26). Therefore, the motivation for a person of ordinary skill in the art to combine the references to inject a botulinum toxin with a needleless syringe for treating wrinkles and brow furrows is the advantage of using needleless injector, which is safer and less pain when compared to injection with a needle as indicated in Vadoud-Seyedi *et al.* Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
November 25, 2004